DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

cc: HFI-35/FOI Staff
DWA

July 18, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-51

Richard J. Sheard
President
Columbus Chemical Industries, Inc.
N4335 Temkin Road
Columbus, Wisconsin 53925

Dear Mr. Sheard:

During a recent inspection conducted by the Food and Drug Administration (FDA) of your facility in Columbus, WI, the investigator found your firm to be repackaging a drug product under significant deviations from Current Good Manufacturing Practice (CGMP) regulations for drug products [Title 21, Code of Federal Regulation, Parts 210 and 211 (21 CFR 210 and 211)]. In addition, subsequent examination of the labeling revealed that your product, Ether USP, (for anesthesia) does not meet the requirements for labeling of a prescription drug product in accordance with the Federal Food, Drug and Cosmetic Act (the Act), Section 503(b)(4).

Ether, USP (for anesthesia) is a drug within the meaning of Section 201(g) of the Act. Your Ether USP (for anesthesia) is adulterated within the meaning of Section 501 (a)(2)(B) of the Act in that the controls used for the manufacture, processing, packaging or holding of the product are not in conformance with 21 CFR 210 and 211.

Our investigator documented deviations from the Current Good Manufacturing Practice regulations, Title 21, Code of Federal Regulations, Parts 210 and 211. These deviations cause your product to be adulterated within the meaning of Section 510(a)(2)(B) of the Act:

1. No identity testing is performed on the incoming bulk Ether USP (21 CFR 211.87).

2. Each lot is not assigned its own unique number to permit the determination of the history and manufacture of the batch [21 CFR 211.130(c)].

3. Ether USP (for anesthesia) is not tested for USP monograph test requirements at the time of repackaging (21 CFR 211.165).

4. Stability testing has not been conducted and the repackaged ether does not contain an expiration date. The lack of these is a violation of 21 CFR 211.137 and 21 CFR 211.166.

A review of the labeling for the Ether USP (for anesthesia) has also revealed violations of the Act. Your product is required to possess a prescription drug legend in accordance with 503(b)(4) unless exempt under 21 CFR 201.100. Additionally, the product you distribute is not packaged in accordance with current USP requirements. USP 23, p. 637, states,

> NOTE: Ether to be used for anesthesia must be preserved in tight containers of not more then 3 KG capacity and is not to be used for anesthesia if it has been removed from the original container longer than 24 hours. Either to be used for anesthesia may, however, be shipped in larger containers for repackaging in containers as directed above, provided that ether at the time of repackaging meets the requirements for the tests of this Pharmacopeia.

This letter is not meant to be all-inclusive. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Failure to do so may result in enforcement action without further notice. This includes seizure and /or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you advise us in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within the requested time frame, you must promptly inform this office of the reason for the delay and the time when each violation will be corrected.

Your reply should be addressed to Acting Compliance Officer Rhonda L. Mecl at the address indicated on the letterhead. Ms. Mecl may be reached at (612) 334-4100 x 159.

Sincerely,

Edwin S. Dee
Acting Director
Minneapolis District

ESD/ccl